DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Detroit District
300 River Place
Suite 5900
Detroit, MI 48207
Telephone: 313-393-8100
FAX: 313-393-8139

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HAND DELIVERED AND
CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
2004-DT-04

January 30, 2004

David C. Jantz, D.C., Partner
Ron S. Kosloff, Partner
Better Than Formula, Inc.
51 Belleview St.
Mt. Clemens, MI 48043

Dear Dr. Jantz and Mr. Kosloff:

The Food and Drug Administration (FDA) has reviewed the labels and labeling of your Better than Formula Ultra Infant Immune Booster 117. Based on our review of your product label and labeling we have concluded that you are in violation of 21 U.S.C. 350a(c) (section 412(c) of the Federal Food, Drug, and Cosmetic Act (the act)) because your product is a new infant formula for which a notification is required under 21 U.S.C. 350a(c) and 21 CFR 106.120. Failure to provide the notice required under 21 U.S.C. 350a(c) is a prohibited act under 21 U.S.C. 331(s). In addition, your product is misbranded under 21 U.S.C. 343(a) of the act in that it is labeled as a dietary supplement and fails to meet the statutory definition for "dietary supplement" under 21 U.S.C. 321(ff) because the product is represented to be a conventional food and sole item of a meal or the diet, i.e., the product is represented to be an "infant formula" within the meaning of 21 U.S.C. 321(z).

The term "dietary supplement" is defined in 21 U.S.C. 321(ff). 21 U.S.C. 321(ff)(1) provides that the term means a product (other than tobacco) intended to supplement the diet that bears or contains a vitamin, mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake. or a concentrate, metabolite, constituent, extract, or combination of any of the above ingredients. 21 U.S.C. 321(ff)(2) further states that dietary supplement means products that are intended for ingestion in a form described in 21 U.S.C. 350(c)(1)(B)(i) or in compliance with 21 U.S.C. 350(c)(1)(B)(ii), are not represented as a conventional food or as a sole item of a meal of the diet, and are labeled as a dietary supplement.

Even though you have labeled your product using the term "a dietary supplement," your product does not meet the statutory definition of a dietary supplement in that it is represented as an infant formula, which is a conventional food. First, it is labeled using the term "Better than Formula," which describes your product as a substitute for or

alternative to other infant formulas. Second, in the label section entitled "mixing instructions and directions" you state that "As with adults, infants should have small feedings every 2 to 3 hours throughout the day and should never be overfed." This statement represents the product for use as a sole item of a meal or the diet. Finally, you explicitly refer to your product as "the finest infant formula available today" and compare the quantity of nutrients in your formula with those of other commercial brands in a promotional brochure. In this brochure and another, you also present your product as an appropriate formula for use by infants who are not or cannot be breast fed. Finally, in the second brochure under "frequently asked questions," you state that a child can take your product "until your child would normally be off of commercial formula and exclusively on solid foods." You also provide a cost estimate of your formula compared to other leading commercial infant formulas based on four-8 oz. servings per day. Taken together, the representations you are making for your product make it clear that your product is being represented for use as an infant formula, a conventional food, and as a sole item of a meal or the diet, and is, therefore, excluded from the statutory definition of dietary supplement under 21 U.S.C. 321(ff)(2)(B).

Your product is an infant formula defined in 21 U.S.C. 321(z). The term "infant formula" means a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk." Moreover, it is a "new infant formula" under 21 U.S.C. 350a(c)(2)(A) because it is an infant formula manufactured by a person which has not previously manufactured an infant formula. Under 21 U.S.C. 350a(c)(1), no person shall introduce or deliver for introduction into interstate commerce any new infant formula unless such person registered with the FDA and, at least 90 days before marketing such new infant formula, made the submission to FDA required by 21 U.S.C. 350a(c)(1). Failure to provide the notice required under 21 U.S.C. 350a(c) is a prohibited act under 21 U.S.C. 331(s).

We request that you take prompt action to correct this and any other violations associated with Better than Formula Ultra Infant Immune Booster 117.

Further, as a manufacturer of an infant formula, under 21 U.S.C. 412(e), you must notify FDA of any knowledge that you have that reasonably supports the conclusion that the infant formula that has left an establishment subject to your control may not provide the nutrients required by 21 U.S.C. 412 (i) or may be otherwise adulterated or misbranded. If FDA finds that the infant formula presents a risk to human health, you would be required to comply with the recall provisions in 21 CFR 107. Failure to notify FDA under 21 U.S.C. 412(e) is a prohibited act under 21 U.S.C. 331(s).

We note that you have agreed to recall your product to the consumer level, and provided a copy of the recall letter to the Detroit District Office. You should continue to advise the Detroit District recall coordinator as to the progress of the recall. Representatives of our office will be available to provide assistance in the development of a strategy for disposing of the recalled product.

Failure to immediately cease distribution of the product could result in enforcement action by FDA without further notice. The Act provides for seizure of violative products, injunction against the manufacturers and distributors of violative products, and criminal sanctions against persons responsible for causing violations of the Act.

We request that you advise us in writing, within 15 days of receipt of this letter, as to the specific steps that have been or will be taken to correct these violations, including the steps taken to recall the product and an explanation of each step taken to assure that similar violations do not recur. Any questions should be directed to David M. Kaszubski, Compliance Branch Director, telephone (313) 393-8110 at the Detroit District Office.

Sincerely yours,

Joann M. Givens
District Director
Detroit District

cc:

[redacted] Owner

[redacted]